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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,626	07/24/2003	Steven P. Adams	14406-003005	9041

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FISH & RICHARDSON P.C.  
1425 K STREET, N.W.  
11TH FLOOR  
WASHINGTON, DC 20005-3500

EXAMINER
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COPPINS, JANET L

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/625,625

Applicant(s)

STEVEN P. ADAMS ET AL

Examiner

Janet Coppins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7, 10 and 11 is/are allowed.
- 6) ☒ Claim(s) 8 and 12-15 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/24/2003.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1-15 pending in the instant application.

#### ***Information Disclosure Statement***

1. Receipt is acknowledged of Applicants' Information Disclosure Statement (IDS), submitted 7/24/2003, which is in compliance with 37 CFR 1.97. Accordingly, the IDS has been considered by the Examiner and entered of record in the file.

#### ***Election/Restrictions***

2. The instant application is a continuation of 09/935,461, now U.S. Pat. No. 6,306,840. Applicants have drawn the instant claims to compounds according to Groups II and IV, wherein X is -COOH, -SO<sub>2</sub>R<sub>5</sub> or -SO<sub>3</sub>H, Y is -CO- and R<sub>1</sub>-R<sub>4</sub> have no carbocyclic aryl or heterocyclic groups.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 12-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an agent for inhibiting or suppressing a cell adhesion-associated disease in a mammal utilizing a stabilized pharmaceutical composition, does not reasonably provide enablement for an agent which prevents such diseases through use of the composition. In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

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1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

5. In the instant case, applicants are claiming a composition that is an agent for “preventing” cell adhesion-associated diseases. The nature of the invention is of a pharmaceutical for the treatment of a disease, i.e. diabetes. As stated, however, the claim asserts that the composition is capable of preventing cell adhesion-associated diseases, or to keep from happening. The state of the art does not teach the absolute prevention of such diseases as multiple sclerosis and diabetes, and in fact teaches away from prevention. Thus any claim to the prevention of the disclosed cell adhesion-associated diseases is highly unpredictable given the current state of the art.

Furthermore, applicant states that the invention may be used in the prevention of each of the diseases listed in claim 15 but does not provide examples as such. Because neither the prior art nor the current application provide sufficient guidance to one of ordinary skill in the art as to the absolute prevention of all of the cell adhesion-associated diseases listed in claim 15, the quantity of experimentation for such a claim is considered to be undue and thus, not enabled.

6. Regarding claims 12-15, the Applicants’ specification does not contain any test results or experimental data showing that the instant compounds will in fact, prevent, inhibit, or suppress cell adhesion in a healthy mammal who does not have a problem, or especially in a mammal not presently at risk of or predisposed to the developing condition. Applicants can overcome this rejection by including the phrase “in need thereof” after “in a mammal” in line 2 of claim 12.

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7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 8 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites the limitation "the cell adhesion inhibitory compound according to claim 1, wherein Y is -CO-, -CH<sub>2</sub>- or -SO<sub>2</sub>-." There is insufficient antecedent basis for this limitation in the claim, since claim 1 does not recited the moieties -CH<sub>2</sub>- or -SO<sub>2</sub>- in the definition of the Y variable.

#### *Claim Objections*

9. Applicant is advised that should claim 8 be found allowable, claim 9 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). If claim 8 is amended to delete the rejected moieties from the Y variable, then claim 9 will be reciting the same subject matter as claim 8.

#### *Conclusion*

10. Claims 1-7 and 10-11 appear allowable over the prior art, claims 8 and 12-15 stand rejected, and claim 9 is objected to.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Joseph McKane (acting for Alan L. Rotman) can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins  
February 6, 2004

*for*   
~~Alan L. Rotman~~ *Joseph McKane*  
Supervisory Patent Examiner, AU 1625